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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/828,699	04/21/2004	Karen M. Cheves	1001.1705101	5388

28075 7590 06/02/2010

CROMPTON, SEAGER & TUFTE, LLC
1221 NICOLLET AVENUE
SUITE 800
MINNEAPOLIS, MN 55403-2420

EXAMINER	
GILBERT, ANDREW M	

ART UNIT	PAPER NUMBER
3767	

MAIL DATE	DELIVERY MODE
06/02/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/828,699	CHEVES ET AL.	
	Examiner	Art Unit	
	ANDREW M. GILBERT	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *21 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/5/2010 has been entered.

Acknowledgements

1. This office action is in response to the reply filed 5/5/2010.

2. Claim 15 was amended.

3. Thus, claim 15 is pending for examination.

Claim Rejections - 35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

2. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated by Wu et al (2004/0243156).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

5. Wu et al discloses a cutting balloon catheter (Fig 2), comprising: an elongate catheter shaft 12); a balloon (114) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration (Fig 2-4), wherein the balloon has a plurality of substantially smooth wings formed therein when in the second configuration (Fig 2-4; [0030]; and response to arguments below); a metallic cutting blade (16) for severing or breaking up a lesion affixed to the balloon throughout the entire use of the cutting balloon catheter (Fig 2-4; Summary), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (16; Fig 2-4), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (16; Fig 2-4); wherein the means for cutting and means for gripping are defined by a series of undulations (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42) on the cutting blade in the first inflated configuration; and wherein the undulations curve from side-to-side relative to the longitudinal axis in the first inflated configuration(16; Fig 2; wherein the cutting members

shown have matching waves as waves 44 on wings 42). See response to arguments below.

6. Claim 15 is rejected under 35 U.S.C. 102(e) as being anticipated or, in the alternative, under 35 U.S.C. 103(a) as obvious over by Shaw et al (7279002) . Shaw et al discloses a cutting balloon catheter (Summary; Fig 12), comprising: an elongate catheter shaft (Fig 12); a balloon (152) coupled to the shaft, the balloon having a first inflated configuration and a second non-inflated configuration (Fig 25; col 7-8), wherein the balloon has a plurality of substantially smooth wings formed therein when in the second configuration (Fig 25); a metallic cutting blade (104; Fig 3) for severing or breaking up a lesion affixed to the balloon throughout the entire use of the cutting balloon catheter (col 3, lns 57-col 4; wherein the Examiner notes that the "affixed to the balloon" means that the metallic cutting blade is attached physically to the balloon in some manner -- the cutting blade 104 on stent 100 is attached to the balloon during use), the cutting blade including means for cutting having two intersecting planes which form a cutting edge, including means for gripping thereon and having a longitudinal axis (104; Fig 3, 5), and having a cross-sectional shape that is substantially triangular in a plane traverse to the longitudinal axis (104; Fig 3, 5); wherein the means for cutting and means for gripping are defined by a series of undulations in the first inflated configuration (104; Fig 3) on the cutting blade; and wherein the undulations curve from side-to-side relative to the longitudinal axis in the first inflated configuration (104; Fig 3). Shaw et al desires a system that includes a cutting stent (col 2, lns 39-45) that can be

expanded to different deployment characteristics (col 4, lns 63-67) including different expanded states such as a first expanded state that incises the stenosis and does not deploy the stent. The device of Shaw et al is fully capable of incising the stenosis and withdrawing the device without deploying the stent – although it is unclear that Shaw et al explicitly discloses a desirability to not deploy the stent in certain situations. One of ordinary skill in the art at the time of the invention would have found it obvious to modify Shaw et al to not deploy the stent in medical treatments where after incising a stenosis provides sufficient treatment so that deploying the stent is unnecessary. Thus, the metallic cutting blade remains affixed to the balloon throughout the entire use of the cutting balloon catheter.

Response to Arguments

3. Applicant's arguments with respect to claim 15 in view of Shaw et al have been considered but are moot in view of the new ground(s) of rejection and discussion above.

4. Applicant's arguments with respect to claim 15 in view of Wu have been considered but are not persuasive.

7. The Applicant argues that:

   i. Wu does not teach a cutting blade with a series of undulations curving from side-to-side relative to the longitudinal axis in the first inflated configuration.

8. In response to (i), the Examiner notes that Wu discloses a cutting blade with a series of undulations curving from side-to-side relative to the longitudinal axis in the first

inflated configuration (16; Fig 2; wherein the cutting members shown have matching waves as waves 44 on wings 42). The cutting members are made of a cutting structure, such as a metallic cutting blade similar to a knife, that has a rigid structure ([0018]). There is no expectation that the undulations in the cutting member will change between first and second configurations because a metallic cutting blade similar to a knife will maintain its shape due to its material composition, which is far different from the material composition of the balloon ([0020]). Thus, the applicant's arguments are not persuasive. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANDREW M. GILBERT whose telephone number is (571)272-7216. The examiner can normally be reached on 8:30 am to 5:00 pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Andrew M Gilbert/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767